Commissioner for Patents United States Patent and Trademark Office Washington, D.C. 20231 www.uspto.gov

JAN 22 2001

Charles W. Ashbrook Assistant General Counsel, Pharmaceutical Patents WARNER-LAMBERT CÓMPANY Parke-Davis Pharmaceutical Research Division 2800 Plymouth Road Ann Arbor MI 48105

Re: Patent Term Extension

Application for

U.S. Patent No. 4,559,334

Dear Mr. Ashbrook:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,559,334 for a period of 1,601 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products).

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Tyson

Senior Legal Advisor

Office of Patent Legal Administration

Office of the Assistant Commissioner for Patent Examination Policy

cc:

David T. Read

Re: OMNICEF TABLETS® (cefdinir) FDA Docket No. 98E-0754

Acting Director Regulatory Policy Staff, CDER

Food and Drug Administration 1451 Rockville Pike, HFD-7

Rockville, MD 20852

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE EXTENDING PATENT TERM UNDER 35 U.S.C. § 156

PATENT NO.

4,559,334

ISSUED

December 17, 1985

INVENTORS

Takao Takaya et al.

PATENT OWNER

Fujisawa Phramaceutical Co., Ltd.

PRODUCT

OMNICEF TABLETS® (cefdinir)

This is to certify that an application under 35 U.S.C. § 156 has been filed in the U.S. Patent and Trademark Office, requesting extension of the term of U.S. Patent No. 4,559,334 based upon the regulatory review of the product OMNICEF TABLETS® (cefdinir) by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

1,601 days

from December 17, 2002, the original expiration date of the patent, subject to the provisions of 35 U.S.C. § 41(b), with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).

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I have caused the seal of the U.S. Patent and Trademark

Office to be affixed this 19th day of January 2001.

Q. Todd Dickinson

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office